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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,451	12/20/2001	Jesper Z. Haeggstrom	PVZ-006US	4167

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EXAMINER	
TALAVERA, MIGUEL A	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,451	HAEGGSTROM ET AL.	
	Examiner	Art Unit	
	Miguel A. Talavera	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36 and 38-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36 and 38-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/27/02, 12/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. In response to the previous Office action, a written restriction requirement (mailed on February 23, 2006), Applicants filed a response/election and amendment received on April 24, 2006. Said amendment cancelled claim 37 and amended claims 36, 38-40 and 49-52. Claims 36 and 38-59 are pending in the instant Office action.

2. In response to a notice to comply with sequence rules, Applicants amendment to the specification, filed on 10/14/05, is acknowledged.

Election/Restriction

3. Applicant's election with traverse of Group II, claim 36-59, filed on April 24, 2006, is acknowledged.

4. RESPONSE TO TRAVERSE: By virtue of applicant amendments to the claims, the lack of unity required under 35 U.S.C. § 121 and 372 is withdrawn.

5. Claims 36 and 38-59 are being examined on the merits.

Information Disclosure Statement

6. The information disclosure statements (IDS) filed on 12/27/02 and 12/27/05 has been reviewed, and the references have been considered as shown by the Examiner's initials next to each citation on the attached copy

Priority

7. This application is a 371 national stage application of PCT/SE00/00384, filed on February 28, 2000, and claims the benefit of US Provisional application 60/122,110, filed on February 26, 1999. The invention finds support in said US Provisional application.

The instant application is granted the benefit of priority for the foreign application filed in Sweden on February 26, 1999 as requested in the declaration.

As 12 months after the US Provisional and foreign filing dates (i.e., February 26, 2000) was a Saturday, the effective date becomes the next business day (Monday; February 28, 2000). Thus, the US Provisional and foreign priority claims are proper.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 36 and 38-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 36 provides for a method of "designing a drug capable of affecting LTA4 hydrolase protein activity" and claim 49 provides for a method of "identifying a compound capable of interacting with a LTA4 hydrolase protein", but, since the claims do not set forth any active method steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. No specific criteria or parameters are set forth to accomplish the purpose of these claims: "designing a drug capable of affecting LTA4 hydrolase protein activity"

or "identifying a compound capable of interacting with a LTA4 hydrolase protein". It is unclear what steps for either "designing a drug" or "identifying a compound" are intended to apply various techniques (i.e., molecular modeling, directed structure based design and combinatorial chemistry). Further, the recited limitations of "capable of affecting" in claim 36 and "capable of binding to" in claim 49 are vague and indefinite. It is unclear what Applicants' intend such language to encompass, wherein absent are criteria(s)/parameter(s) that is considered to identify a chemical or biochemical species as "capable of affecting" or "capable of binding to". A claim is indefinite where it merely recites a process or method without any active, positive steps delimiting how this process or method is actually practiced. In order to avoid rejection under 35 USC 112 2nd paragraph applicant is invited to amend the method and process claims to set forth clear, distinct and positive process steps that clearly relates to the preamble of the claim(s). Claims 38-48 dependent from claim 36 and claims 50-59 dependent from claim 49 are also included in the instant rejection because they fail to correct the noted deficiencies. Clarification of the metes and bounds, via clearer claim language, is requested.

9. Claim 38 and 50 are unclear in regards to the Table reciting specific amino acid residues. What does "left wall" and "right wall" mean? None of these terms are clearly defined in the art; nor are explicit definitions found in the specification. Similarly, what are the meaning rows 1-8? Why is it numbered 1-8? Clarification is requested.

10. Claim 38-40 and 50-52 recite amino acid residues positions without providing a SEQ ID NO or a reference protein sequence. Because different laboratories may have different numbering of the same protein, said recitations are indefinite and ambiguous. Clarification or correction is requested.

11. Claim 42 recites "conventional organic synthesis" which in the absence of a clear definition of the metes and bounds of this phrase it is unclear which conditions for such synthesis are actually claimed. For example, how does one distinguish the conditions for designing a drug employing unconventional organic synthesis? Further, the recited limitation of "refining the structure of the product of the synthesis by cycles of crystallization of the LTA4 hydrolase and either the inhibitor or agonist" is unclear as to how cycles of crystallization refine the structure of the product? If applicant's intention is to use cycles of X-ray crystallographic analysis of crystalline LTA4-drug complexes, applicant is invited to amend the method and process claims to set forth clear, distinct and positive process steps that clearly relates to such purpose. Clarification is required.

12. Claims 41 and 43-48 are confusing because it is unclear as to how a skilled artisan would know *a priori* that the compound "designed" by the method of claim 36 would agonize or inhibit LTA4 hydrolase or treat a disease. Clarification is requested.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 36 and 38-59 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention.

Written Description

14. Claims 36 (claim(s) 38-48 rejected as being dependent therefrom) and 49 (claim(s) 50-59 rejected as being dependent therefrom) are drawn to methods "for designing a drug capable of affecting LTA_4 hydrolase protein activity" and "for identifying a compound capable of interacting with LTA_4 hydrolase protein", respectively, by "utilizing" a genus of molecular structures (herein three-dimensional models) comprising a "functional equivalent part" of LTA_4 hydrolase protein.

The Court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." UC California v. Eli Lilly, (43 USPQ2d 1398). For claims drawn to a genus, M.P.E.P. § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.,* structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. M.P.E.P. § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire

genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

15. A description of a protein three-dimensional model, i.e., "functional equivalent part thereof", using functional language, i.e., "capable of exhibiting enzymatic activity", in the absence of a specific structure is not considered sufficient to show possession of the claimed invention. It is noted that the instant specification discloses the full-set of structural coordinates of LTA4H as set forth in Table 9, used in the claimed method. However, the instant specification does not disclose the structure coordinates of LTA4H as directed to the "functional equivalent part thereof". The examples in the specification do not provide written basis for a three-dimensional model having the limitation of "functional equivalent part thereof" from the three-dimensional structure of the full-length LTA4H; in essence, the specification simply directs those skilled in the art to go figure out for themselves what the claimed "functional equivalent part thereof" looks like. The instant specification fails to satisfy the written description requirement wherein a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

16. Similarly, the claims 43-48, 53 and 55-59 encompass a genus of drugs/compounds defined only by their intended use/function, i.e., treating or preventing a wide range of disorders. There is no evidence that there is any *per se* structure/function relationship between the disclosed bestatin, the specific inhibitors of Example 3 (i.e., thiolamine and hydroxamic acid), and any others that might be found using the claimed method that are useful in treating/preventing a wide range of disorders as encompassed by claims 43-48, 53 and 55-59. There is no description of an

actual reduction to practice, each step of the claimed method or distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated protein three-dimensional model and compound possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves of a "functional equivalent part thereof" and the structural commonality of the compounds encompassed by claims 43-48, 53 and 55-59 are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). A description of what a material does rather than of what it is, usually does not suffice. See Fiers, 984 F.2d at 1169-71, 25 USPQ2D at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many species may achieve that result. The definition requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 /f.2d 1516, 1521, 22 USPQ 369, 372-73 (Fed. Cir. 1984) affirming the rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what the material consists of (e.g. structural feature), is not a description of that material.

Scope of Enablement

17. Claims 36 and 38-59 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the full-set of structural coordinates of a human LTA_4 hydrolase protein (listed in Table 9), does not reasonably provide enablement for all structural coordinates defining a molecular structure of a functional equivalent the human LTA_4 hydrolase protein.

Initially, it is noted that M.P.E.P. § 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted "functionally equivalent part thereof" or "functionally equivalent part" in claims 36, 38-40 and 49-52 as meaning that the resulting 3-D structures generated from the recited structural coordinates encompass any protein described by a structural homology model of LTA hydrolase or a model of any functional truncation of LTA hydrolase. Claims 54 recite the language "a selected region thereof". Meriam-Webster Online Dictionary defines "region" as:

> "**6 :** an open connected set together with none, some, or all of the points on its boundary."

Thus, the word "region" does not impart any structural limitations on the molecular structure and encompasses widely variant molecular structures ranging from a single atom to full-length LTA_4 hydrolase protein as set forth in Table 9.

18. In order to identify, select, and design by studying the interaction of a species (i.e. compound) with a molecular structure of a functional equivalent of a human LTA_4 hydrolase protein one skilled in the art would require the three dimensional structure coordinates of all functional equivalent thereof. Applicants have failed to provide guidance to obtain the atomic

coordinates of all functional equivalent of a human LTA_4 hydrolase protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). M.P.E.P. § 2164.04 states, "[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection" and that "[t]he language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims." Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: Claims 36 (claim(s) 38-48 rejected as being dependent therefrom) and 49 (claim(s) 50-59 rejected as being dependent therefrom) to methods "for designing a drug capable of affecting LTA_4 hydrolase protein activity" and "for identifying a

compound capable of interacting with LTA_4 hydrolase protein", respectively, by "utilizing" a genus of three-dimensional models comprising a "functional equivalent part" of LTA_4 hydrolase protein, which include any protein described by a structural homology model (i.e., evolutionary relatedness) of LTA hydrolase or a model of any functional truncation of LTA hydrolase. The enablement provided by the specification is not commensurate in scope with the claims with regard to the three-dimensional models of a functional equivalent part of LTA_4 hydrolase protein as broadly encompassed by the claims. In this case, the specification is enabling only for a computational method for evaluating the ability of a compound to associate with a three-dimensional models consisting of the full-set three-dimensional coordinates of human LTA_4 hydrolase protein (as set forth by atom 1 to atom 4876 in Table 9) and specific active sites as defined in Tables 1-3.

The state of the prior art; The level of one of ordinary skill; and The level of predictability in the art: At the time of the invention, *in silico* screening methods for identifying compounds that bind to a defined binding pocket were known in the art (see for example, Balaji *et al.* US Patent 5,579,250 and Itai *et al.* US Patent 5,642,292). While such methods of structure-based screening of compounds using defined target three-dimensional models representative of the natural state of the target are known in the prior art, knowledge of clearly defined target models for the claimed genus of a "functional equivalent part" of LTA_4 hydrolase protein is lacking in the specification. While methods of generating homology models of a protein using a set of structure coordinates was known, Lambert et al. (US Patent Application Publication 2004/0137518) acknowledges that "[p]otential or existent homology models cannot provide the necessary degree of specificity" in the *in silico* design of modulators (p. 3, ¶[0017]).

It is well established in the arts of *in silico* screening that obtaining a potential associating species without a clearly defined target three-dimensional model is highly unpredictable. That is, it would appear to be highly unpredictable as to whether all three-dimensional models of a "functional equivalent part" of LTA_4 hydrolase protein having unrestricted structure and atomic composition, would be useful for identifying a compound that interact with LTA_4 hydrolase. Searching among any and all possible "functional equivalent part" models for a target model that is suitable for the evaluation, identification or design of a compound is well outside the realm of routine experimentation and predictability in the art of success in is extremely low. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus of "functional equivalent part" models in order to use such members.

The amount of direction provided by the inventor and The existence of working examples: The application does not provide sufficient direction to one of ordinary skill in the art on how to make/use any molecular structure of a functional equivalent of a human LTA_4 hydrolase protein. The specification is devoid of any teaching beyond the full-set three-dimensional coordinates of human LTA_4 hydrolase protein (as set forth by atom 1 to atom 4876 in Table 9) and specific active sites thereof as specifically defined in Tables 1-3. No teachings are provided as to how to use any functional equivalent of a human LTA_4 hydrolase to design a drug. Absent is the manner/procedures the one of skill in the art would derive all other three-dimensional coordinates of "functional equivalent thereof". Again, in such absence one of skill in the art would be required to perform further undue experimentation to derive the three-dimensional coordinates of all other said polypeptides.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of in silico screening for potential associating species were known in the art at the time of the invention, it was not routine to screen for binding compounds using a three-dimensional structure of a "functional equivalent part" of a LTA_4 hydrolase protein and to screen those compounds by a trial and error process with no expectation that those compounds will have the ability to bind to LTA_4 hydrolase protein or affect its enzymatic activity.

In the absence of adequate guidance and working examples by which to derive all other three-dimensional coordinates of "functional equivalent thereof" one of skill in the art would be required to utilize inventive skill for such derivation by identifying or designing molecular structures of a "functional equivalent thereof" through the formulation of independent decisions and judgements about the criteria(s)/parameter(s), and to test & validate these derived polypeptides. Such independent decisions, judgments, tests, & validation are not routine and is considered undue experimentation. Applicants are directed to Fields, Wilkinson, and Kende v. Conover and Woodward [170 USPQ 276; How-to-Make Requirement section] which states:

> "the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Therefore, in view of the deficiencies as addressed above one of skill in the art would be unable to derive all three-dimensional coordinates of "functional equivalent thereof".

19. It is also noted that, claims 43-48, 53 and 55-59 encompass a genus of drugs/compounds defined only by their intended use/function, i.e., treating or preventing a

wide range of disorders, wherein the relationship between the structural features of the members of the genus and said use/function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have identify/design a compound of interest using the claimed methods does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity/function as encompass by claims 43-48 and 53-59.

Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior ad are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 36, 38-41 and 43-59 are rejected under 35 U.S.C. § 103(a) as being unpatentable

over Balaji *et al.* (US Patent 5,579,250, Balaji) in view *In re Gulack* 217 USPQ 401 (Fed. Cir. 1983) and *In re Ngai* 70 USPQ2d 1862 (Fed. Cir. 2004). The claims are drawn to a computational based method for identifying or designing a compound capable of binding a LTA_4 hydrolase protein using atomic structure coordinates of human LTA_4 hydrolase protein.

Balaji teaches methods of rational drug design via computer modeling. Specifically, columns 11-32 detail the use of atomic coordinates of a receptor - such as a protein - wherein drugs or compounds which interact therewith are designed using structural coordinate data obtained from, e.g., X-ray crystallography. Polypeptide modeling is specifically discussed in column 24, line 50, through column 25, line 26. In columns 11-32, energy minimization, bond angles, etc. are discussed as parameters in said design methods, including those of making and contacting compound with protein. These descriptions are encompassed by the instant methods, only missing the specific structural coordinates as disclosed in Table 9.

In *Gulack* and *Ngai*, the court held that nonfunctional descriptive material in a claim does not distinguish the prior art in terms of patentability. The key factor in analyzing the obviousness of these claims over the prior art is the determination that the computer algorithm used to identify compounds that may bind LTA_4 hydrolase protein is a known algorithm and is unmodified. If the difference between the prior art and the claimed invention as a whole is limited to descriptive material stored on or employed by a machine, it is necessary to determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material. In this case, the structural coordinates disclosed in Table 9 are nonfunctional descriptive material and the method uses a known unmodified computer algorithm. Data, which are fed into a known algorithm whose purpose is to compare or modify those data using a series

of processing steps, do not impose a change in the processing steps and are thus nonfunctional descriptive material. A method of using a known comparator for its known purpose to compare data sets does not become non-obvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See M.P.E.P. § 2106 and Cases 6-7 of the "Report on comparative study on protein three-dimensional structure related claims" of the "Trilateral Project WM4 Comparative studies in new technologies" at www.trilateral.net/projects/biotechnology/protein_3d/wm4_3d_annex_3.pdf

As non functional data used in a known algorithm do not modify any of the processing steps, and simply changing the data to be processed is not beyond the ordinary skill in the art, it would have been obvious at the time of the invention to perform rational drug design as taught by Balaji to result in an compound that interacts with LTA_4 hydrolase protein, wherein only nonfunctional descriptive material is additionally present in the claims, which do not distinguish the claimed methods from Balaji according to *In re Gulack and In re Ngai.*

Conclusion

21. Claims 36 and 38-59 are rejected for the reasons identified in the numbered sections of the Office action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Miguel A. Talavera whose telephone number is (571)272-3354. The examiner can normally be reached on M-F, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on (571)272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER

Miguel A. Talavera, Ph.D.
June 6, 2006